

REMARKS

Claims 1-21 are pending in the application. Claims 16-18 were previously withdrawn from consideration. Claims 1 and 15 have been amended by way of the present amendment. Reconsideration is respectfully requested.

In the outstanding Office Action, claims 1-3, 5-7, 9-15, 19 and 21 were rejected under 35 U.S.C. Section 112, 2nd paragraph; 35 U.S.C. Section 103(a) as unpatentable over U.S. Patent No. 3,605,123 (Hahn). Reconsideration is respectfully requested.

112 Claim Rejections

Claims 1-3, 5-7, 9-15, 19 and 21 were rejected under 35 U.S.C. Section 112, 2nd paragraph. Reconsideration is respectfully requested.

Claims 1 and 5 were amended to remove language, such as “substantial” and “is designed with” that are indicated as indefinite in the outstanding Office Action. Therefore, it is respectfully submitted that the claims are now definite and it is respectfully requested that the outstanding rejections be withdrawn.

103 Claim Rejections

Claims 1-3, 5-7, 9-15, 19 and 21 were rejected under 35 U.S.C. Section 103(a) as unpatentable by Hahn. Applicants respectfully traverse the rejection.

Claims 1 and 15 have been amended to clarify the invention. In particular, claim 1 has been amended to recite:

wherein the layer is established on an undulating or uneven surface (3') present on the implant and having a roughness value in the range of 0.4 - 5 μm , for the purpose of increasing the a total layer volume of the layer to a range between 5×10^{-2} and 10^{-5} cm^3 , wherein the channel network (6) is designed with has mouths (3', 4') on a surface of the layer adjacent to the bone or tissue structure and whose respective cross-sectional diameters (D) are in the range of 0.1 μ to 10 μm at the surface (2a') of the layer, wherein the cross-sectional diameters of the mouths are given different sizes to create conditions for bone growth with a predefined penetration function,

~~wherein the mouths of the channel network is designed with have the mouths having cross-sectional diameters that are substantially less than the respective depths of the channels in and down into the layer as seen from said surface (2a'), and~~

wherein the diameters of the mouths and the depths of the channels stimulate bone growth by means of diffusion and contribute to the incorporation of the implant in the bone or tissue structure, and

~~wherein the channel network (6) comprises a combination of contiguous channel branches (12, 13, 14, 15, 16) which extend in at least both vertical and lateral directions within the layer (2'') and toward a transition (11) between the layer (2'') and the implant (1').~~

Claim 15 has been amended with similar language. Support for the amendments is provided at least at page 7, line 37 to page 9, line 6, and as shown at least in **FIG. 4** of the specification.

Therefore, the amendments raise no questions of new matter.

Hahn discloses a permanent implant for bone tissue which has a dense cast or wrought base portion of high strength metal, and a porous metal layer overlying and bonded to the base portion.¹ In particular, Hahn discloses a prosthesis **10** that includes a pin or shaft **11** and ball **12**.² In addition, Hahn discloses the prosthesis **10** may be composed of metals such as titanium.³

Further, Hahn discloses the titanium prosthesis **10** is coated, on the pin or shaft **11**, with a *thin* porous layer of titanium **13**.⁴ In particular, Hahn discloses, that at the interface between the shaft **11** and layer **13** is, for practical purposes free of pores or interstices.⁵ Further, Hahn discloses that the pores will range from about 30 microns to about 200 microns wide at the opening or mouth.⁶ Furthermore, Hahn discloses that the coating thickness is approximately 0.1 inch and the preferred thickness is from about 0.015 to about 0.030 inches.⁷

Moreover, Hahn discloses a process for providing a high strength bond between the coating **13** and base metal shaft **11** using a plasma flame. In particular, Hahn discloses *no*

¹ Hahn at Abstract.

² *Id.* at column 3, lines 30-33.

³ *Id.* at column 3, lines 33-35.

⁴ *Id.* at column 3, lines 43-45.

⁵ *Id.* at column 3, lines 55-58.

⁶ *Id.* at column 3, lines 63-66.

⁷ *Id.* at column 3, lines 47-54.

porosity or practically no porosity exists at the interface between the coating **13** and surface of the base metal shaft **11** and gradually increasing porosity, along with pore size and pore density, in moving away from the interface between the surface of the base metal and the coating **13**. Furthermore, Hahn discloses renderings of actual photographs of magnified sections of bone **20**, **30**; pin or shaft **21** and coating **22**, **32**.⁸

However, Hahn nowhere discloses, as recited in claim 1:

wherein the layer is established on an undulating or uneven surface present on the implant and having *a roughness value in the range of 0.4 - 5 μm , for the purpose of increasing a total volume of the layer to a range between 5×10^{-2} and 10^{-5} cm^3 ,*

wherein the channel network (6) has mouths (3', 4') on a surface of the layer adjacent to the bone or tissue structure and whose respective cross-sectional diameters (D) are in the range of 0.1 μ to 10 μm at the surface (2a') of the layer,

wherein the cross-sectional diameters of the mouths are given different sizes to create conditions for bone growth with a predefined penetration function,

wherein the mouths of the channel network have cross-sectional diameters that are less than the respective depths of the channels in and down into the layer as seen from said surface (2a'),

wherein the diameters of the mouths and the depths of the channels stimulate bone growth by means of diffusion and contribute to the incorporation of the implant in the bone or tissue structure, and

wherein the channel network (6) comprises a combination of contiguous channel branches (12, 13, 14, 15, 16) which extend in at least both vertical and lateral directions within the layer (2'') and toward a transition (11) between the layer (2'') and the implant (1') (emphasis added).

Independent claim 15 has been similarly amended. That is, Hahn nowhere discloses “having a roughness value in the range of 0.4 - 5 μm , for the purpose of increasing a total volume of the layer to a range between 5×10^{-2} and 10^{-5} cm^3 ,” and “the cross-sectional diameters of the mouths are given different sizes to create conditions for bone growth with a predefined penetration function” and “the channel network (6) comprises a combination of contiguous

⁸ *Id.* at FIG. 2, FIG. 3; column 3, lines 55-66; and column 5, lines 25-42.

channel branches (12, 13, 14, 15, 16) which extend in at least both vertical and lateral directions within the layer (2'') and toward a transition (11) between the layer (2'') and the implant (1')."

Thus, it is respectfully submitted that Hahn does not disclose, anticipate or inherently teach the limitations of claims 1-3, 5-7, 9-15 and 19-21. Therefore, it is respectfully submitted that independent claims 1 and 15, and claims dependent thereon, patentably distinguish over Hahn.

Conclusion

In view of the above amendments and remarks, reconsideration and allowance of the pending claims are respectfully requested.

Applicants believe that the present application is in condition for allowance, and an early indication of the same is respectfully requested.

If the Examiner has any questions or requires clarification, the Examiner may contact the undersigned so that this Application may continue to be expeditiously advanced. In the event the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned is available at the telephone number noted below.

The Director is hereby authorized to charge any fees, or credit any overpayment, associated with this communication, including any extension fees, to Deposit Account No. 22-0185.

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Respectfully submitted,

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